



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0020]

Monsanto Co.; Determination of Nonregulated Status of Soybean Genetically Engineered for Increased Yield

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a soybean event developed by the Monsanto Company, designated as MON 87712, which has been genetically engineered for increased yield, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Monsanto Company in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and the comments we received at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0020> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence

Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 11-202-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Biotechnology Environmental Analysis Branch, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: rebecca.l.stankiewicz-gabel@aphis.usda.gov. To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 11-202-

01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of soybean (Glycine max) designated as MON 87712, which has been genetically engineered for increased yield. The petition states that this soybean is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of genetically engineered (GE) organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the Federal Register on July 13, 2012, (77 FR 41354-41355, Docket No. APHIS-2012-0020), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending on September 11, 2012, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received 66 comments on the petition. Several of these comments included electronic attachments consisting of a consolidated document of many identical or nearly identical letters, for a total of 4,665 comments. APHIS decided, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new

¹ On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

² To view the notice, the petition, the comments we received, and other supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0020>.

issues. According to our public review process for such petitions (see footnote 1), APHIS first solicits written comments from the public on a draft environmental assessment (EA) and plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and PPRA and other information, APHIS revises the PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

In a notice (see footnote 2) published in the Federal Register on August 5, 2013, (78 FR 47272-47273, Docket No. APHIS-2012-0020), APHIS announced the availability of a PPRA and a draft EA for public comment. APHIS solicited comments on the draft EA, the PPRA, and whether the subject soybeans are likely to pose a plant pest risk for 30 days ending on September 4, 2013. APHIS received one comment during the comment period. The comment did not address the regulatory status of MON 87712 soybean, but rather raised concerns regarding APHIS' authority to regulate GE plants and the Agency's NEPA process. APHIS has addressed the issues raised during the comment period and has provided responses to this comment as an attachment to the FONSI.

National Environmental Policy Act

After reviewing and evaluating the comment received during the comment period on the draft EA and PPRA and other information, APHIS has prepared a final EA. The EA has been

prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Monsanto's MON 87712 soybean. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of MON 87712 soybean).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Monsanto's MON 87712 soybean is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of November 2013.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

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